Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Evaluation of effects of topical solution of vitamin E in preventing oral mucositis in Allogenic Hematopoietic Stem Cell Transplantation patients

Protocol summary

Study aim

The aim of the current study is to find a new way to prevent the occurrence of mucositis and decrease its severity in recipients of hematopoietic stem cell transplant who receive conditioning regimen with the combination of Busulfan and Cyclophosphamide.

Design

Two arm parallel,randomized double blind placebo controlled clinical trial

Settings and conduct

This study is going to take place in Bone Marrow Transplantation center of Tehran. Patients included in this study are supposed to receive a topical solution that contains Vitamin E or placebo, twice daily and be evaluated each day by the researcher in order to examine the effects of topical vitamin E on the occurrence and severity of the oral mucositis. Preparation of the topical solution is going to be done by department of Pharmaceutics in Faculty of Pharmacy. The chief of research and Pharmaceutics expert will be the only ones aware of the formulation content and will make proper decisions based on the circumstances.

Participants/Inclusion and exclusion criteria

Inclusion criteria: - Age more than 18 years - Receiving conditioning regimen with Busulfan and Cyclophosphamide Exclusion criteria: - Patients with active mucositis at the time of admission - Active bleeding - Any contraindications to vitamin E, including history of hypersensitivity reactions to drug or any component of the formulation

Intervention groups

In this study, patients are going to be divided into two groups. patients in the test group will receive a topical solution that contains vitamin E 400 IU twice daily and are supposed to rinse their mouth with the solution and spit it out. The patients in the placebo group are going to receive an identical looking solution that does not contain vitamin E.

Main outcome variables

- Decreased incidence and severity of oral mucositis - Decreased need for narcotic pain killers - Decreased length of ward stay

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180416039325N1**
Registration date: **2018-07-25, 1397/05/03**
Registration timing: **registered_while_recruiting**

Last update: **2018-07-25, 1397/05/03**
Update count: **0**

Registration date

2018-07-25, 1397/05/03

Registrant information

Name
Mohammad Solduzian
Name of organization / entity
Country
Iran (Islamic Republic of)
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+98 21 6694 6218
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-07-23, 1397/05/01

Expected recruitment end date

2019-07-23, 1398/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of effects of topical solution of vitamin E in preventing oral mucositis in Allogenic Hematopoietic Stem Cell Transplantation patients

Public title

Effects of topical vitamin E solution in mucositis

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Age older than 18 years Receiving conditioning regimen with Busulfan and Cyclophosphamide

Exclusion criteria:

Showing active mucositis signs and symptoms at the time of admission Active bleeding Any contraindication to vitamin E as hypersensitivity reactions

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

The patients are going to be divided into blocks of 8 patients. For randomization a random numbers table is going to be utilized. Patients who will receive the odd numbers are going to be given the product labeled as number 1 and patients who will receive the even numbers are going to be given the product labeled as number 2. Allocation concealment is carried out by blinding the researcher.

Blinding (investigator's opinion)

Double blinded

Blinding description

In the current study, the pharmaceutical products containing drug or placebo are going to be formulated in Tehran University of Medical Sciences, Faculty of Pharmacy and delivered to the researcher. Neither the patient, attending nurse or researcher are going to be aware of which product contains the drug. The head of the clinical trial and pharmaceutics expert will be aware of the patients status including which one receives the drug or placebo and will make proper decisions to proceed with the trial or discontinue it based on situation and inform the related authorities.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tehran University of Medical Sciences

Street address

North Kargar st, Jalal st, Sahriaty Hospital, Hematology- Oncology and Bone Marrow Transplant Center,Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1411713135

Approval date

2018-05-06, 1397/02/16

Ethics committee reference number

IR.TUMS.TIPS.REC.1397.017

Health conditions studied

1

Description of health condition studied

Oral mucositis

ICD-10 code

K12.3

ICD-10 code description

Oral mucositis (ulcerative)

Primary outcomes

1

Description

Incidence of oral mucositis

Timepoint

Daily for 15 days which is the duration that patient receives the formulation

Method of measurement

Clinical evaluation based on National Cancer Institute Common Terminology Criteria for Adverse Effects version 4.0 scale

2

Description

Severity of oral mucositis

Timepoint

Daily for 15 days which is the duration that patient receives the formulation

Method of measurement
Clinical evaluation based on National Cancer Institute Common Terminology Criteria for Adverse Effects version 4.0 scale

Secondary outcomes

1

Description
Duration of Bone Marrow Transplant ward stay
Timepoint
From the day of admission to Bone Marrow Transplant ward until discharge form the ward
Method of measurement
Medical records

2

Description
The need for narcotic analgesic
Timepoint
From the day of admission to Bone Marrow Transplant ward until discharge form the ward
Method of measurement
Medical records

Intervention groups

1

Description
Intervention group: Patients in the intervention group are supposed to receive vitamin E mouth wash solution, that contain 400 IU of the drug in each dose, twice daily and be evaluated daily by the researcher in order to find the effects of vitamin E on the incidence and severity of oral mucositis. The mouth wash solution contains glycerin, sodium chloride, sodium benzoate and polysorbate 20 in water base.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
shariaty hospital
Full name of responsible person
Moluk Haji Babayi
Street address
North Kargar st, Jalal AL Ahmad st, Tehran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Moluk Haji Babayi
Position
Professor
Latest degree
Specialist
Other areas of specialty/work
Medical Pharmacy
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
Not applicable
Title and more details about the data/document
Evaluation of effects of topical solution of vitamin E in preventing oral mucositis in allogenic Hematopoietic Stem Cell Transplantation patients.
When the data will become available and for how long
the data of the study is anticipated to be available in 6/15/2019 and be available indefinitely
To whom data/document is available
the plan is to publish the results of the research in valid data bases and make available for fellow researchers from different fields
Under which criteria data/document could be used
the private data that belongs to patients is not going to be available to anyone and different analysis could be performed on the provided data under proper referencing rules.
From where data/document is obtainable
publishable data or documents could be obtained by contacting through the following routes: - email: m-solduzian@razi.tums.ac.ir - phone number: 00989120920355
What processes are involved for a request to access data/document
the request should be submitted to above mentioned e.mail or phone number, and the required information must be verified by the chief of research, then the data will be available only if ethic committee proves it is publishable.
Comments